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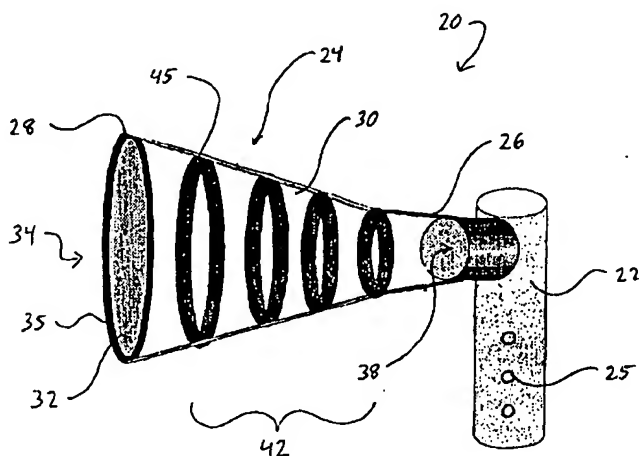
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- Declaration under Rule 4.17:**  
— of inventorship (Rule 4.17(iv)) for US only
- Published:**  
— with international search report  
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

[Continued on next page]

(54) Title: NONINVASIVE INTRADUCTAL FLUID DIAGNOSTIC SCREEN



(57) Abstract: Disclosed is a method and apparatus for accomplishing a noninvasive screen for breast disease markers, including breast cancer markers and cytologically abnormal cells. Intraductal fluid is noninvasively aspirated using compression, heating, and suction cycles. The removed sample is thereafter assayed for the presence of cytologically abnormal cells and/or one or more breast disease markers. Sample size and intraductal mobility of breast disease markers may be enhanced by retrograde introduction of a carrier. A portable, self-contained intraductal fluid aspiration device (20) includes a housing (22), one or more controls and/or indicators (25), and a patient or breast interface (24) having a tissue contacting surface (32) for receiving

a breast and a second concavity (38) for receiving a nipple. Preferably, the breast interface (24) is provided with a dynamic compression zone (42), having one or more compression elements (45) for compression in the mid breast region to facilitate intraductal fluid aspiration.



(88) Date of publication of the international search report:  
20 February 2003

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/16900

| <b>A. CLASSIFICATION OF SUBJECT MATTER</b>  |   |  |
|---|---|--|
| IPC(7) : C12Q 1/00; A61M 1/00   |   |  |
| US CL : 435/4; 604/74   |   |  |
| According to International Patent Classification (IPC) or to both national classification and IPC   |   |  |
| <b>B. FIELDS SEARCHED</b>   |   |  |
| Minimum documentation searched (classification system followed by classification symbols)<br>U.S. : 435/4; 604/74   |   |  |
| Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched                                 |   |  |
| Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>Please See Continuation Sheet |   |  |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>   |   |  |
| Category *  | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No.  |
| X   | US 6,221,622 B1 (LOVE) 24 April 2001 (24.04.2001), abstract, columns 2 - 3  | 1, 24 - 25, 27 - 32  |
| ---   |   |  |
| Y   |   | 24, 26   |
| Y   | US 5,798,266 A (QUAY et al.) 25 August 1998 (25.08.1998), abstract, columns 4 - 5   | 24, 26   |
| A   | US 2001/0001059 A1 (LOVE) 10 May 2001 (10.05.2001), entire document   | 1 - 32   |
| A, P  | US 6,391,026 B1 (HUNG et al.) 21 May 2002 (21.05.2002), entire document   | 1 - 32   |
| A, P  | US 6,328,709 B1 (HUNG et al.) 11 December 2001 (11.12.2001), entire document  | 1 - 32   |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.                         |   |  |
| * Special categories of cited documents:  |   |  |
| "A"   | document defining the general state of the art which is not considered to be of particular relevance  | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |
| "E"   | earlier application or patent published on or after the international filing date   | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |
| "L"   | document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "O"   | document referring to an oral disclosure, use, exhibition or other means  | "&" document member of the same patent family  |
| "P"   | document published prior to the international filing date but later than the priority date claimed  |  |
| Date of the actual completion of the international search   |   | Date of mailing of the international search report   |
| 26 November 2002 (26.11.2002)   |   | 12 DEC 2002  |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. (703)305-3230          |   | Authorized officer:<br>Ruth A. Davis<br>Telephone No. 703-308-0196   |

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/16900

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: 1 - 32
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐  
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

PCT/US02/16900

### BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-2, drawn to a method for screening breast cancer.

Group II, claims 3-15, drawn to a screening device.

Group III, claims 16-21, drawn to a screening device.

Group IV, claims 22-23, drawn to a screening device.

Group V, claims 24-27, drawn to a method to increase yield in breast ductal aspiration.

Group VI, claims 28-32, drawn to a method for enhancing transport of intraductal indicium of a disease.

Group VII, claims 33-35 and 40, drawn to a method for screening breast cancer.

Group VIII, claims 36-39, drawn to a method for introducing therapeutics into a breast duct.

The inventions listed as Groups I - VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claims are drawn to several different screening devices and method which do not share a special technical feature. No special technical feature exists, since each of the groups are drawn to unrelated devices and methods.

### Continuation of B. FIELDS SEARCHED Item 3:

CAS-STN, WEST Database

search terms: intraductal breast fluid, aspiration, device, pump, cancer, disease, screen, nipple aspiration, suction, vacuum, therapeutic